

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR CONFIRMATION NO. Terry A. Guinan P1046 US 2802 09/965,473 09/26/2001 EXAMINER 03/21/2005 7590 Medtronic AVE, Inc. BAXTER, JESSICA R 3576 Unocal Place ART UNIT PAPER NUMBER Santa Rosa, CA 95403 3731

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

ſ.
<u>প্রে</u>

	Application No.	Applicant(s)	
Office Action Summary	09/965,473	GUINAN ET AL.	
	Examiner	Art Unit	
	Jessica R Baxter	3731	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) Responsive to communication(s) filed on <u>28 December 2004</u> .			
2a)⊠ This action is FINAL . 2b)□ This action is non-final.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application.			
4a) Of the above claim(s) is/are withdrawn from consideration.			
5) Claim(s) is/are allowed.			
6)⊠ Claim(s) <u>1-20</u> is/are rejected.			
7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some * c) ☐ None of: 1.☐ Certified copies of the priority documents have been received.			
Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)			
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)			
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152) 6) Other:			
S. Datest and Trademark Office			

Application/Control Number: 09/965,473

Art Unit: 3731

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 1-3, 6-11, 14-17, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,464,718 to Miller et al.

Miller discloses a balloon having a flexible wall, proximal and distal cones (FIGS. 5-7), proximal and distal ends adapted for being mounted to a catheter, an intermediate body configured to receive a stent (22) thereon, said stent having a proximal end and a distal end, at least one circumferential groove formed on the balloon wall between one of the proximal end and the distal end of the stent (Column 5 line 37-Column 6 line 11) and the respective proximal and distal cone for mechanically disengaging the respective cone from the intermediate body allowing each to move differently in a radial direction (Column 4 lines 31-46) wherein said at least one circumferential groove is present when the balloon is in an inflated and a deflated state. Miller also discloses creating dams by inflating the proximal and distal cones and thus retaining the stent on the balloon (Column 4 lines 41-46). Miller also discloses that the groove is formed before the stent is mounted on the balloon (Column 6 lines 37-47).

Application/Control Number: 09/965,473 Page 3

Art Unit: 3731

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 4, 5, 12, 13 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. '718 in view of U.S. Patent No. 6,254,608 to Solar.

Miller discloses the claimed invention except for the flexible material comprising a foamed material. Solar teaches that a foamed material is used for bonding the stent to the catheter to allow the stent to become embedded in the balloon in order to protect the anatomical passageways during delivery of the stent and prevent the stent from slipping without the use of a protective sheath (Column 3 line 44 – Column 4 line 2 and Column 5 lines 20-24). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the balloon catheter of Miller with the foamed material of Solar in order to protect the anatomical passageways during stent delivery and prevent the stent from slipping off the balloon without the use of a protective sheath.

Response to Arguments

- 5. Applicant's arguments filed December 28, 2004 have been fully considered but they are not persuasive.
- 6. Applicant argues that Miller et al. '718 does not disclose circumferential grooves. Miller discloses placing a ghost stent on the balloon to form a stent nest in the balloon. The stent Nest will have circumferential grooves that conform to the shape of the struts of the stent (Column 5 line 52-

Column 6 line 48). The balloon as it is heated will conform to the shape of the stent and provide the enhanced retention with a circumferential groove at each end of the balloon. These grooves are created by each end of the stent. The grooves will be present in the inflated or deflated state since they are created by heating and reshaping the balloon and allowing the balloon to conform to the shape of the stent.

7. Applicant argues that Miller et al. '718 does not disclose " the respective proximal and distal cone for mechanically disengaging the respective cone from the intermediate body allowing each to move differently in a radial direction." The device of Miller allows the cones to inflate at different rates and pressures (Column 4 lines 31-67). Since it takes different inflation pressures and rates to inflate the different portions of the balloon, the device of Miller is considered to have cones that are mechanically disengaged from the intermediate portion. The rejection of claims 1-3, 6-11, 14-17, 19 and 20 over Miller et al.'718 is thus proper.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter Examiner Art Unit 3731

ANHTUANT. NGUYEN
SUPERVISORY PATENT EXAMINER

Jirb